



WHI HRT Update

2002

WHI Hormone Program

The WHI Hormone Program is studying two types of hormone pills. One is estrogen plus progestin in women who *had not* had a hysterectomy before joining the WHI. The other is estrogen alone in women who already *had* a hysterectomy before joining. This "Update" describes new information about the estrogen plus progestin study.

Hormone Program Results Reviewed

The WHI Data and Safety Monitoring Board (DSMB) recently reviewed the health status of women in the Women's Health Initiative. Based on this review, the DSMB recommended that:

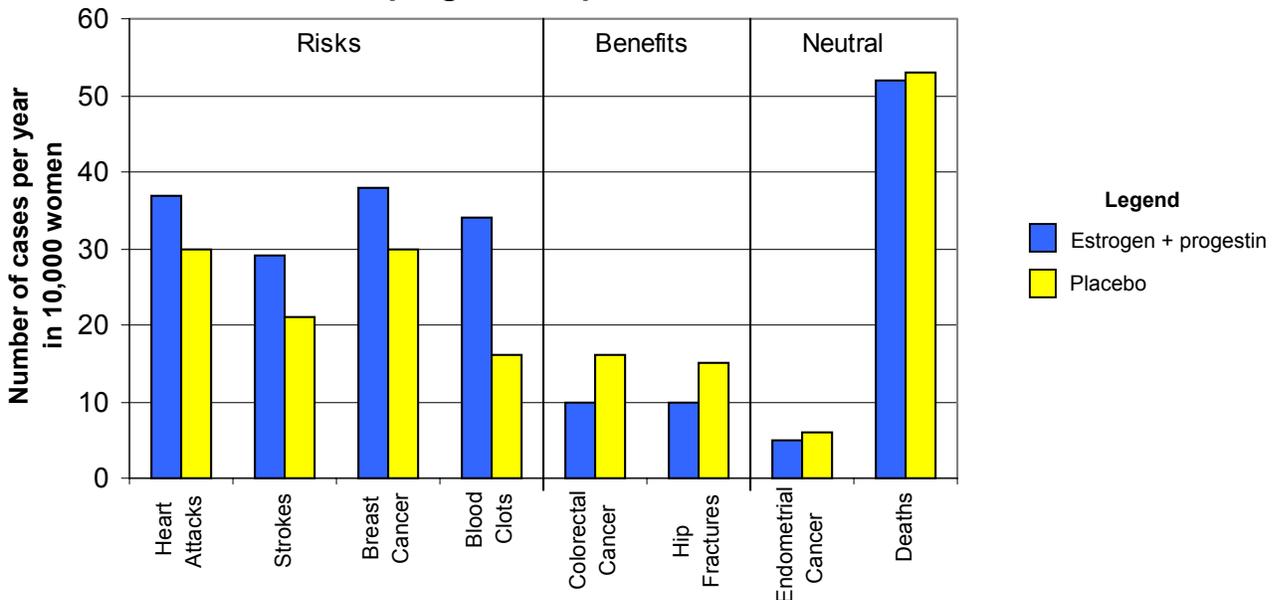
- Women in the study of *estrogen plus progestin stop* their study pills, because the risks now exceed the benefits.
- Women in the study of *estrogen alone continue* taking their study pills as before, because it remains uncertain whether the benefits outweigh the risks.

Assessing Risks and Benefits

In trying to understand the overall balance of risks and benefits of *estrogen plus progestin*, the DSMB reviewed information on many health conditions. Earlier "HRT Updates" told you about the effects of hormones on heart attacks, strokes, and blood clots. Now an important increase in breast cancer for women on estrogen plus progestin has become clear.

The graph below shows how often certain health events occurred in women taking estrogen plus progestin (darker bars) and in women taking placebo or inactive pills (lighter bars). Heart attacks, strokes, blood clots, and breast cancer occurred in more women on estrogen plus progestin. Fewer women on these hormones had colorectal cancer and hip fractures. There were no differences in the number of women who had endometrial cancer or in the number of deaths.

Disease rates for women on estrogen plus progestin or placebo



How many women were affected?

Only 2.5% of women in the estrogen plus progestin study had these health events. These results tell us that during one year, for every 10,000 women taking estrogen plus progestin, we would expect:

- 7 more women with heart attacks. In other words, 37 women taking estrogen plus progestin would have heart attacks compared to 30 women taking placebo.
- 8 more women with strokes.
- 8 more women with breast cancer.
- 18 more women with blood clots.

These results also suggest that for every 10,000 women taking estrogen plus progestin, we would expect:

- 6 fewer colorectal cancers.
- 5 fewer hip fractures.
- Fewer fractures in other bones.

In summary, then, more women taking estrogen plus progestin had a serious health event than did women taking placebo. We conclude that estrogen plus progestin does not prevent heart disease and is not beneficial overall.

These results do not apply to women who had a hysterectomy before joining WHI and are participating in the study of estrogen alone.

The DSMB recommended that the study of estrogen alone continue as planned. The balance of risks and benefits for women in the estrogen alone study is still uncertain. *It is important to note that, to date, women in the estrogen alone study have not shown an increased risk of breast cancer.*

What does this mean for me?

If you are in the estrogen plus progestin Hormone Program, you should stop taking your study pills. You are in this part of the program if you had not had a hysterectomy before joining the WHI. We also ask you to

provide us with “Medical History Update” information so that we can study all the serious health events that occurred up to this point. Also, please return the “Signature Sheet” with this form. Your clinic staff will let you know how to return any left-over study pills. You should continue having your yearly mammograms and WHI clinic exams. Even though you stop your study pills, your ongoing participation is important because it will help us learn how these effects change after you stop your study pills.

If you are in the estrogen alone Hormone Program, please continue taking your study pills as before and having your yearly mammograms and WHI clinic exams. Your efforts will help us learn whether the overall benefits of taking estrogen alone exceed the risks. This question is as important now as ever.

If you are in other WHI programs, everything else stays the same. Nothing has changed for you. There are many more questions about women’s health that need to be answered. These answers will help women and their doctors make better decisions about women’s health.

How can I find out more?

This update reviews the information available now. You may find additional details on the World Wide Web (<http://www.whi.org>). WHI scientists will also do more data analyses over the coming weeks and months. As these results become available, we will inform you through newsletters and updates to the study website.

Thank you!

Thank you for taking part in this landmark study of women’s health. The time and effort you have given to the WHI has made it possible to answer one of many important health questions for postmenopausal women in the United States.



We have more work to do and hope that you will join with us in continuing this effort.